JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS156
		Effective Date	10/19/2022
		Approval Date	10/19/2022
	Subject **Radicava ORS**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Radicava oral, Radicava ORS

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I. POLICY

Radicava ORS (edaravone) will require prior authorization to ensure it is used only when clinically appropriate. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Radicava ORS** may be approved for patients meeting the following:
   1. Documentation has been submitted showing the following:
      a. Patient has a diagnosis of definite or probable amyotrophic lateral sclerosis (ALS)
      b. Patient has scores of at least 2 points on all 12 areas of the revised ALS Functional Rating Scale (ALSFRS-R)
      c. Patient does not require continuous use of noninvasive or invasive ventilatory support during the day and night
   2. Prescriber is, or has consulted with, a neurologist, neuromuscular specialist, or physician specializing in the treatment of ALS

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
B. Approval for continuation of therapy may be extended in 12-month intervals with documentation showing the patient has had a positive clinical response to Radicava therapy, and invasive ventilation is not required

IV. EXCLUSIONS

A. Radicava ORS will not be approved for the following:
   1. Any indications or uses that are not FDA-approved or guidelines-supported
B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

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V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. REFERENCES

1. Radicava and Radicava ORS [prescribing information]. Jersey City, NJ: MT Pharma America, Inc.; May 2022.
2. EFNS Task Force on Diagnosis and Management of Amyotrophic Lateral Sclerosis; Andersen PM, et al. EFNS guidelines on the Clinical Management of Amyotrophic Lateral Sclerosis (MALS) – revised report of an EFNS task force. Eur J Neurol. 2012;19(3):360-75.
3. Writing Group, Edaravone (MCI-186) ALS 19 Study Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomized, double-blind, placebo-controlled trial. Lancet Neurol. 2017; 16:505-512.

VII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
10/19/2022	Policy Creation

Review Date: 10/19/2022

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